

**REMARKS**

Claims 11-26 are pending in the present application. Claims 13-16, 18, 19, 23, 25, and 26 have been canceled, Claims 11, 12, 17, and 24 have been amended, and Claims 27-32 have been added, leaving Claims 11, 12, 17, 20-22, 24, and 27-32 for consideration upon entry of the present Amendment. Claim 11 has been amended to limit the upper respiratory disease to sinusitis and rhinitis, and to correct a simple typographical error. Support for the amendment made to Claim 11 is found at Page 4, lines 92-94 of the Specification as originally filed. Claim 12 has been amended to provide another pharmaceutically acceptable vehicle. Support for the amendment made to Claim 12 is found at Page 1, lines 1-6 of the Specification as originally filed. Dependent Claim 17 was amended to provide proper reference to the terminology used in the corresponding independent Claim 11. Therefore, support for the amendment is found in Claim 11 as originally filed. Support for the amendment made to Claim 24 is found Page 1, lines 18-22 of the Specification as originally filed. No new matter has been introduced by these amendments.

The Specification has been amended in answer to the Examiner's objections to the Specification. The amendments made, and support thereof, is provided in detail below in answer to the Examiner's objections. Additionally, the 3<sup>rd</sup> full paragraph on Page 2 of the Substitute Specification has been amended to provide proper antecedent support for currently amended Claim 24. Support for this amendment is found at Page 1, lines 18-22 of the Specification as originally filed. No new matter has been introduced by these amendments.

The additional claims have been made for the purpose of further claiming the invention, rather than to overcome any rejections related to patentability. Support for new Claim 27 is found in Claims 1 and 9 as originally filed. Support for new Claims 28-32 is found in the specification and claims as originally filed. Accordingly no new matter is introduced by these claims.

Reconsideration and allowance of the claims is respectfully requested in view of the above amendments and the following remarks.

Constructive Election

The Examiner has withdrawn Claim 26 from consideration as being drawn to a non-elected invention. The Examiner states that the invention has been constructively elected by original presentation for prosecution on the merits, and that Claim 26 is directed to an invention that is independent of these claims as it is directed to a composition that can be used in other methods. Applicants have canceled claim 26 without prejudice from consideration.

Objections Under 35 U.S.C. § 132

The Examiner objects to the material presented in the amendment filed on September 30, 2002 stating that the amendment added material which is not supported by the original disclosure. In particular, the Examiner objects to Page 2, lines 43-47, stating that the active compound comes in an aqueous solution made of 15% water in 85% acid and that the ideal composition is 70% 1,2,3-propanetriol and 30% 1,2-propanediol. Applicants have canceled this material from the specification without prejudice.

Objection Under 37 C.F.R. § 1.75

The Examiner has advised Applicants that should Claim 11 be allowable, Claim 23 will be objected to as being a substantial duplicate thereof. In order to advance prosecution, Applicants have accordingly canceled Claim 23 without prejudice.

Objections to the Specification

The disclosure is objected to on Page 2, lines 43-44. Applicants respectfully submit that the Examiner's objection on this point is moot in light of Applicants amendment to the Specification.

The Examiner further objects to the Specification stating that it fails to provide proper antecedent basis for the claimed subject matter. In particular, the Examiner states that no support is seen in the specification for the "concentration of 0.2-10 vol%" in Claim 11. Applicants have accordingly amended the 2<sup>nd</sup> full paragraph on Page 2 of the Substitute

Specification as mailed on September 23, 2002. Support for this amendment is found at Page 1, lines 13-17 of the Specification and in Claim 1, both as originally filed. Additionally, Applicants have amended this paragraph to include the limitations set forth in Claim 9 as originally filed. Applicants accordingly request reconsideration and withdrawal of this objection.

The Examiner states that the Specification fails to provide proper antecedent basis for "high airway diseases" as set forth in Claims 15 and 16. Claims 15 and 16, however, have been canceled, thereby making this objection moot.

The Examiner states that the Specification fails to provide proper antecedent basis for "nasal releaser" as set forth in Claim 17. Accordingly, Applicants have amended the 4<sup>th</sup> full paragraph on Page 2 of the Substitute Specification as mailed on September 23, 2002. Support for this amendment is found at Page 5, lines 20-21 of the Specification as originally filed, and in Claim 4 as originally filed. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

The Examiner states that the Specification fails to provide proper antecedent basis for "clearing agent of nasal cavities and cheekbones" as set forth in Claim 19. Claim 19, however, has been canceled, thereby making this objection moot.

The Examiner objects to Claim 11 as line 5 of Claim 11 omits the word "is". Accordingly, Applicants have amended Claim 11 to correct this simple typographical error. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

#### Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 13 and 14 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in relevant art that the inventors, at the time the applications was filed, had possession of the claimed invention. In particular, the Examiner states that no support is seen in the originally filed disclosure for the amount of alpha-hydroxypropionic acid of Claim

13 and the 70 ml of 1,2,3-propanotril and 30 ml of 1,2-propanodiol of Claim 14. Applicants have rendered the Examiner's rejections moot by canceling Claims 13 and 14 without prejudice.

Claims 11-24 also stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the specification, while enabling for a method of treating sinusitis and rhinitis, does not reasonably provide enablement for treating all upper respiratory disease. In order to advance prosecution, Applicants have amended Claim 11 to claim a method of treating sinusitis and rhinitis, and have canceled Claim 25 as recommended by the Examiner. Applicants, thereby, request reconsideration and withdrawal of this rejection.

#### Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 15-19 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

In particular, the Examiner states that in Claims 15 and 16, it is unclear what the recitation "high airway" diseases means. Applicants respectfully submit that the Examiner's argument on this point is moot in light of the cancellation of Claims 15 and 16.

The Examiner states that in Claims 15 and 24, the word "includes" renders the claims indefinite because it is unclear whether the limitations following the word are part of the claimed invention. Applicants have canceled Claim 15 without prejudice, thereby making the Examiner's rejection on this point moot. Applicants have amended Claim 24 to advance prosecution.

Claim 19 has been rejected as the Examiner states that it is not clear what is meant by "clearing agent of nasal cavities and cheekbones." Applicants have canceled Claim 19 without prejudice, thereby making the Examiner's rejection moot.

#### Claim Rejections Under 35 U.S.C. § 103(a)

Claims 11-25 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over

DE 2721014 to Reith ("Reith"). The Examiner states that the reference discloses that alpha-hydroxy propionic acid can be used to treat allergies and viral diseases. Applicants respectfully traverse this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Establishing a prima facie case of obviousness requires that all elements of the invention be disclosed in the prior art. *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A 1970). Applicants' Claim 11 sets out in part: "A method of treating sinusitis and rhinitis... comprising administering to a nasal passageway... a composition comprising alpha-hydroxypropionic acid and a pharmaceutically acceptable vehicle...." Therefore, in order to establish a prima facie case of obviousness, Reith must disclose, at the very least, a method of treating sinusitis and rhinitis.

Reith teaches new medicaments consisting of (a) dextrorotatory lactic acid and/or a salt thereof; (b) Echinacea purpurea and/or Echinacea angustifolia; and, optionally, (c) usual pharmaceutical carriers and/or diluents (English Abstract). The medicaments can be used for desensitization or hypersensitization in allergic states, e.g., allergies to plasters, metals, pollen, flowers, animals, animal hair, bee stings, or drugs (English Abstract). They are also suitable for the treatment of viral diseases (English Abstract).

Although Reith teaches medicaments for the treatment of allergies and viral infections, it does not teach or suggest a method for treating sinusitis and rhinitis. Applicants submit that sinusitis and rhinitis refers to highly localized inflamed regions of the facial area, which are not taught or suggested by Reith. Therefore, as Reith does not teach or suggest Applicants' claimed method for treating sinusitis and rhinitis, a prima facie case of obviousness has not been established for Claim 11. Additionally, Applicants assert that as dependent claims incorporate all of the limitations of the claim from which they depend, not all elements of dependent Claims 12, 17, 20-22, and 24 are taught or suggested by Reith. Accordingly, a prima facie case of obviousness has not been established for these claims. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 11, 12, 17, 20-22, and 24.

In light of the foregoing amendments and remarks, reconsideration by the Examiner is respectfully requested. It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' attorneys.

Respectfully submitted,

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